IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Dr. Reddy's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Dr. Reddy's seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Ozempic® prior to the expiration of United States Patent Nos. 8,129,343 (the "'343 patent"), 8,920,383 (the "'383 patent"), 9,132,239 (the "'239 patent"), 9,457,154 (the "'154 patent"), 9,687,611 (the "'611 patent"), 9,775,953 (the "'953 patent"), 10,220,155 (the "'155 patent"), 10,335,462 (the "'462 patent"), 11,097,063 (the "'063 patent"), and RE46,363 (the "'363 patent") which cover *inter alia*, Ozempic® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

3. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

5. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

6. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Defendant Dr. Reddy's Laboratories, Ltd.

7. On information and belief, Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. acted in concert to prepare and submit ANDA No. 216417 ("Dr. Reddy's ANDA") to the FDA.

8. On information and belief, following any FDA approval of Dr. Reddy's ANDA, Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. will act in concert to distribute and sell a generic version of semaglutide injection, 2 mg/1.5 ml and 4 mg/3 ml ("Dr. Reddy's Product") throughout the United States, including within Delaware.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Defendant Dr. Reddy's Laboratories, Inc. by virtue of, *inter alia*, its presence in Delaware, having conducted business in the State of Delaware; and having engaged in systematic and continuous contacts with the State of Delaware; previously consenting to personal jurisdiction in this Court; and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see e.g.*, *Novartis Pharms. Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 19-02053 (D. Del. Oct. 29, 2019); *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 20-00847 (D. Del. June 24, 2020)).

11. This Court has personal jurisdiction over Defendant Dr. Reddy's Laboratories, Ltd. by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court (*see e.g.*, *Novartis Pharms. Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 19-02053 (D. Del. Oct. 29, 2019)); and having taken advantage of the rights and

protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see e.g.*, *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 20-00847 (D. Del. June 24, 2020); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc.*, C.A. No. 19-02045 (D. Del. Oct. 29, 2019)).

12. On information and belief, Dr. Reddy's intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Dr. Reddy's Product, directly or indirectly, throughout the United States and in this District. Dr. Reddy's filing of Dr. Reddy's ANDA confirms this intention and further subjects Dr. Reddy's to the specific personal jurisdiction of this Court.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

14. On March 6, 2012, the United States Patent and Trademark Office issued the '343 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '343 patent.

15. On December 30, 2014, the United States Patent and Trademark Office issued the '383 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '383 patent.

16. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '239 patent.

17. On October 4, 2016, the United States Patent and Trademark Office issued the '154 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is

attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '154 patent.

18. On June 27, 2017, the United States Patent and Trademark Office issued the '611 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '611 patent.

19. On October 3, 2017, the United States Patent and Trademark Office issued the '953 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '953 patent.

20. On March 5, 2019, the United States Patent and Trademark Office issued the '155 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '155 patent.

21. On July 2, 2019, the United States Patent and Trademark Office issued the '462 patent, entitled "Use of Long-Acting GLP-1 Peptides," a copy of which is attached to this Complaint as Exhibit H. NNAS is the owner of all right, title, and interest in the '462 patent.

22. On August 24, 2021, the United States Patent and Trademark Office issued the '063 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit I. NNAS is the owner of all right, title, and interest in the '063 patent.

23. On April 11, 2017, the United States Patent and Trademark Office issued the '363 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit J. NNAS is the owner of all right, title, and interest in the '363 patent.

OZEMPIC®

24. NNI holds approved New Drug Application No. 209637 (the "Ozempic® NDA") for Ozempic® (semaglutide) subcutaneous solution, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml), which NNI sells under the trade name Ozempic®.

25. The claims of the patents-in-suit cover, *inter alia*, Ozempic® and/or its use.

26. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '383, '239, '154, '611, '953, '155, '462, '063, and '363 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Ozempic®.

DR. REDDY'S ANDA

27. On information and belief, Dr. Reddy's submitted ANDA No. 216417 ("Dr. Reddy's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of semaglutide injection, 2 mg/1.5 ml and 4 mg/3 ml ("Dr. Reddy's Product").

28. On information and belief, Dr. Reddy's ANDA refers to and relies upon the Ozempic® NDA and contains data that, according to Dr. Reddy's, demonstrate the bioequivalence of Dr. Reddy's Product and Ozempic®.

29. By letter to NNI and NNAS, dated February 2, 2022 (the "Notice Letter"), Dr. Reddy's stated that Dr. Reddy's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '383, '239, '154, '611, '953, '155, '462, '063, and '363 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture,

use, or sale of Dr. Reddy's Product (the "Paragraph IV Certification"). Dr. Reddy's attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,129,343

30. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-29 of this Complaint.

31. Dr. Reddy's has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '343 patent.

32. Claims 1-2 and 4-5 of the '343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Claims 3 and 6 encompass a method of treating type 2 diabetes comprising administering to a patient an effective amount of semaglutide. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '343 patent would infringe claims 1-6 of the '343 patent.

33. Upon information and belief, Dr. Reddy's sale or offer for sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, or commercial marketing of Dr. Reddy's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Dr. Reddy's Product in the United States, thus inducing infringement of claims 3 and 6 of the '343 patent.

34. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '343 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '343 patent expires.

35. Novo Nordisk has no adequate remedy at law.

36. Dr. Reddy's was aware of the '343 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,920,383

37. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-36 of this Complaint.

38. Dr. Reddy's has infringed the '383 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '383 patent.

39. Claims 1-12 of the '383 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of medicament left in a reservoir in an injection device. Claim 13 of the '383 patent is directed to a syringe device employing such a mechanism. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '383 patent would infringe claims 1-13 of the '383 patent.

40. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '383 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '383 patent expires.

41. Novo Nordisk has no adequate remedy at law.

42. Dr. Reddy's was aware of the '383 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,132,239

43. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-42 of this Complaint.

44. Dr. Reddy's has infringed the '239 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '239 patent.

45. Claims 1-3 of the '239 patent are directed to a dial-down mechanism for an injection device. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '239 patent would infringe claims 1-3 of the '239 patent.

46. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '239 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '239 patent expires.

47. Novo Nordisk has no adequate remedy at law.

48. Dr. Reddy's was aware of the '239 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,457,154

49. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-48 of this Complaint.

50. Dr. Reddy's has infringed the '154 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '154 patent.

51. Claims 1-17 of the '154 patent are directed to an injection device comprising a dose delivering mechanism which provides an audible feedback signal to a user at the end of injection of a set dose. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '154 patent would infringe claims 1-17 of the '154 patent.

52. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '154 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '154 patent expires.

53. Novo Nordisk has no adequate remedy at law.

54. Dr. Reddy's was aware of the '154 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,687,611

55. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-54 of this Complaint.

56. Dr. Reddy's has infringed the '611 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '611 patent.

57. Claims 1-13 and 15 of the '611 patent are directed to an injection device with a torsion spring operatively connected to a dose setting member and a rotatably mounted display member. Claim 14 of the '611 patent is directed to an injection pen comprising a torsion spring and a dose indicator barrel having a helical scale. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '611 patent would infringe claims 1-15 of the '611 patent.

58. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '611 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '611 patent expires.

59. Novo Nordisk has no adequate remedy at law.

60. Dr. Reddy's was aware of the '611 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,775,953

61. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-60 of this Complaint.

62. Dr. Reddy's has infringed the '953 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to

manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '953 patent.

63. Claims 1-10 and 12-25 of the '953 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of medicament left in a reservoir in an injection device. Claim 11 of the '953 patent is directed to a syringe device employing such a mechanism. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '953 patent would infringe claims 1-25 of the '953 patent.

64. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '953 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '953 patent expires.

65. Novo Nordisk has no adequate remedy at law.

66. Dr. Reddy's was aware of the '953 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,220,155

67. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-66 of this Complaint.

68. Dr. Reddy's has infringed the '155 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '155 patent.

69. Claims 1-8 of the ’155 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent ejection of a dose exceeding a set dose. Dr. Reddy’s manufacture, use, offer for sale or sale of Dr. Reddy’s Product within the United States, or importation of Dr. Reddy’s Product into the United States, during the term of the ’155 patent would infringe claims 1-8 of the ’155 patent.

70. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy’s is not enjoined from infringing the ’155 patent and/or if the FDA is not enjoined from approving Dr. Reddy’s ANDA before the ’155 patent expires.

71. Novo Nordisk has no adequate remedy at law.

72. Dr. Reddy’s was aware of the ’155 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,335,462

73. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-72 of this Complaint.

74. Dr. Reddy’s has infringed the ’462 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy’s ANDA, by which Dr. Reddy’s seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy’s Product prior to the expiration of the ’462 patent.

75. Claims 1-10 of the ’462 patent are directed to methods of treating type 2 diabetes by administering a semaglutide solution. Dr. Reddy’s manufacture, use, offer for sale or sale of Dr. Reddy’s Product within the United States, or importation of Dr. Reddy’s Product into the United States, during the term of the ’462 patent would infringe claims 1-10 of the ’462 patent.

76. Upon information and belief, Dr. Reddy's sale or offer for sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, or commercial marketing of Dr. Reddy's Product in the United States, during the term of and with knowledge of the '462 patent, would intentionally induce others to use Dr. Reddy's Product in the United States, thus inducing infringement of claims 1-10 of the '462 patent.

77. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '462 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '462 patent expires.

78. Novo Nordisk has no adequate remedy at law.

79. Dr. Reddy's was aware of the '462 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 11,097,063

80. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-79 of this Complaint.

81. Dr. Reddy's has infringed the '063 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '063 patent.

82. Claims 1-7 of the '063 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent ejection of a dose exceeding a set dose. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United

States, or importation of Dr. Reddy's Product into the United States, during the term of the '063 patent would infringe claims 1-7 of the '063 patent.

83. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '063 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '063 patent expires.

84. Novo Nordisk has no adequate remedy at law.

85. Dr. Reddy's was aware of the '063 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. RE46,363

86. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-85 of this Complaint.

87. Dr. Reddy's has infringed the '363 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to manufacture, use, offer to sell, and sell Dr. Reddy's Product prior to the expiration of the '363 patent.

88. Claims 1-8 of the '363 patent are directed to a dial-down mechanism for an injection device. Claims 9 and 10 of the '363 patent are directed to a medication delivery device comprising such a dial-down mechanism. Claim 11 of the '363 patent is directed to a method for using a wind up injection pen. Dr. Reddy's manufacture, use, offer for sale or sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, during the term of the '363 patent would infringe claims 1-11 of the '363 patent.

89. Upon information and belief, Dr. Reddy's sale or offer for sale of Dr. Reddy's Product within the United States, or importation of Dr. Reddy's Product into the United States, or commercial marketing of Dr. Reddy's Product in the United States, during the term of and with knowledge of the '363 patent, would intentionally induce others to use Dr. Reddy's Product in the United States, thus inducing infringement of claim 11 of the '363 patent.

90. Novo Nordisk will be harmed substantially and irreparably if Dr. Reddy's is not enjoined from infringing the '363 patent and/or if the FDA is not enjoined from approving Dr. Reddy's ANDA before the '363 patent expires.

91. Novo Nordisk has no adequate remedy at law.

92. Dr. Reddy's was aware of the '363 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Dr. Reddy's and respectfully requests the following relief:

A. A judgment that Dr. Reddy's has infringed the '343 patent;

B. A judgment that Dr. Reddy's has infringed the '383 patent;

C. A judgment that Dr. Reddy's has infringed the '239 patent;

D. A judgment that Dr. Reddy's has infringed the '154 patent;

E. A judgment that Dr. Reddy's has infringed the '611 patent;

F. A judgment that Dr. Reddy's has infringed the '953 patent;

G. A judgment that Dr. Reddy's has infringed the '155 patent;

H. A judgment that Dr. Reddy's has infringed the '462 patent;

I. A judgment that Dr. Reddy's has infringed the '063 patent;

J. A judgment that Dr. Reddy's has infringed the '363 patent;

K. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Dr. Reddy's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '343, '383, '239, '154, '611, '953, '155, '462, '063, and '363 patents, including any extensions, adjustments, and exclusivities;

L. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Dr. Reddy's, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Dr. Reddy's Product within the United States, or importing Dr. Reddy's Product into the United States, prior to the expiration of the '343, '383, '239, '154, '611, '953, '155, '462, '063, and '363 patents, including any extensions, adjustments, and exclusivities;

M. If Dr. Reddy's commercially manufactures, uses, offers to sell, or sells Dr. Reddy's Product within the United States, or imports Dr. Reddy's Product into the United States, prior to the expiration of the '343, '383, '239, '154, '611, '953, '155, '462, '063, and '363 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

N. An award of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

O. An award of costs and expenses in this action; and

P. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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